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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,863	10/04/1999	SHAMAY IZHAR	1620/3	8900

28765 7590 02/24/2004

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PATENT DEPARTMENT
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WASHINGTON, DC 20005-3502

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/411,863

Applicant(s)

IZHAR, SHAMAY

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/03 and 12/9/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47, 49, 51, 58, 60 and 62-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49, 51, 60 and 71-79 is/are allowed.
- 6) ☒ Claim(s) 47, 58, 59 and 62-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 47, 49, 51, 58, 60 and 62-79 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claims 59 and 61 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the cancellation of the claims.
4. The objection to claims 59, 61, 64 and 73 because informalities is withdrawn in light of Applicant's amendment or cancellation of the claims.
5. The rejection of claims 47, 49, 51 and 55-79 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of Applicant's amendment to indicate that a nucleic acid encoding recombinase is introduced into the plant, to cancel or amend claims where the exogenes are RNA molecules or encode a transactivator that is non-operable with eukaryotic promoters, and to limit the claims to gene combinations suitable for exogenic allelism other than those involved in making male sterile plant.
6. The rejection of claims 47, 49, 51 and 55-79 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment to limit the methods to methods of producing male sterile plants and the plants to male sterile ones.

Art Unit: 1638

7. The rejection of claims 47, 49 and 56-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment or cancellation of the claims.

Claim Rejections - 35 USC § 102, § 103

8. Claim 58 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gutterson et al (US Patent 6,392,119, filed January, 1997).

Gutterson et al teach a method of generating exogenic allelism comprising crossing a plant comprising a construct comprising a first promoter, a first transcribable nucleic acid, and between the two a second transcribable nucleic acid operably linked to a second promoter, flanked by site-specific recombination sequences, to a plant comprising a nucleic acid encoding a recombinase to generate progeny in which the first promoter and the first transcribable nucleic acid are operably joined, selfing the progeny plant (column 9, lines 48-50) to produce a plant wherein the expression cassette has the third segment excised (column 9, lines 44-48), and backcrossing the selfed progeny to the first plant to generate progeny with exogenic allelism (Fig. 1 and column 8, line 59, to column 10, line 7). The method is described in which the progeny plants are male sterile and female fertile (see Fig. 1). Gutterson et al also teach that the exogenes are to encode proteins that include barnase and ribonuclease T1, or RNAs like anti-sense RNAs and ribozymes (column 14, lines 21-39). The transactivator would be "non-operable with eukaryotic promoters".

Art Unit: 1638

The prior art plants differ from the claimed plants only by their method of manufacture. However, the claimed method of making the plants characterized by exogenic allelism would not distinguish them over the plants taught by the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

9. Applicant's arguments filed 23 July 2003 in response to a rejection of claims 58-59 over Gutterson et al have been fully considered but they are not persuasive.

Applicant urges that Gutterson et al do not teach selecting progeny devoid of recombinase, while the instant invention provides the benefit of increased reliability, preventing sequence reshuffling in the progeny (response pg 10).

This is not found persuasive because regardless of whether Gutterson et al teach selecting progeny devoid of recombinase, at least some of the progeny produced by Gutterson et al would be identical to the instantly claimed plants.

Claim Rejections - 35 USC § 103

10. Claims 47, 58-59 and 62-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutterson et al (US Patent 6,392,119, filed January, 1997) in view of each of Stuurman et al (1996, Plant Mol. Biol. 32:901-913), and Medberry et al (1995, Nuc. Acids. Res. 23:485-490).

The claims are drawn to a method of generating exogenic allelism comprising crossing a plant comprising a construct comprising a first promoter, a first transcribable nucleic acid, and

Art Unit: 1638

between the two a second transcribable nucleic acid operably linked to a second promoter, flanked by site-specific recombination sequences, to a plant comprising a nucleic acid encoding a recombinase to generate progeny in which the first promoter and the first transcribable nucleic acid are operably joined, selfing the progeny plant, selecting a selfed progeny that lacks the recombinase to produce a plant wherein the expression cassette has the third segment excised, and backcrossing the selfed progeny to the first plant to generate progeny with exogenic allelism.

The teachings of Gutterson et al are discussed above. Gutterson et al do not disclose selecting a progeny plant that lacks the recombinase.

Stuurman et al disclose a method of Cre-lox mediated site-specific recombination wherein the resulting inversion DNA, which has two lox sites, must be stabilized in the progeny by selecting those that lack Cre (pg 909, right column, paragraph 2).

Medberry et al disclose a method of Cre-lox mediated site-specific recombination wherein the resulting inversion DNA, which has two lox sites, must be stabilized in the progeny by selecting those that lack Cre (pg 488, right column, paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of generating exogenic allelism as taught by Gutterson et al, to select a progeny that lacks the recombinase, as taught by each of Stuurman et al and Medberry et al. One of ordinary skill in the art would have been motivated to do so Stuurman et al and Medberry et al teach that removal of the recombinase is necessary to prevent further action of the recombinase on the multiple lox sites present in the plants. One of skill in the art would know that the presence of the recombinase in the progeny would mean that when the progeny is

Art Unit: 1638

backcrossed to the first plant, the resulting progeny would be subject to the action of the recombinase and progeny with exogenic allelism would not be produced.

11. Applicant's arguments filed 23 July 2003 and 9 December 2003 and the Declarations of Drs. Yagil, Yesodi and Ohad filed 9 December 2003 in response to a rejection of claims 47, 56, 58-59 and 62-70 under 35 U.S.C. 103(a) as being unpatentable over Gutterson et al (US Patent 6,392,119, filed January, 1997) have been fully considered.

Drs Yagil and Ohad urge that to one of skill in the art selecting progeny devoid of recombinase would not be obvious (Declarations).

This is not found persuasive because each of Stuurman et al and Medberry et al teach that selecting progeny devoid of recombinase is required to stability in plants with multiple recombinase recognition sites, as discussed above.

Applicant and Dr. Yesodi urge that Gutterson does not teach or even suggest that the selection step would be necessary (response pg 9, Declaration pg 12 [Right Fax page numbers used. As Applicant's response of 9 December 2003 and the Declaration of Dr. Yesodi elaborate on the arguments of the response filed 23 July 2003, only arguments from the former two are presented here])

This is not found persuasive because the teachings of Stuurman et al and Medberry et al make it clear that one of skill in the art would know that such a selection step would be necessary to prevent further action of the recombinase on genomes with multiple recombination sites.

Applicant and Dr. Yesodi urge that selecting progeny devoid of recombinase is an active, time-consuming step that is important to stability of the plants generated by the instant process.

Art Unit: 1638

Applicant and Dr. Yesodi urge that given that the step is expensive and time-consuming, if the prior art knew its importance, one would expect a teaching in the prior art of this step (response pg 9, Declaration pg 12-13).

This is not found persuasive, as steps well-known in the art to be required may not be explicitly stated, even if they are time consuming. The rejection has been restated using secondary references that make it clear that one of skill in the art would know that such a selection step is necessary to prevent sequence reshuffling in the progeny.

It is noted that Applicant's responses and the Declaration urges that selection of progeny devoid of recombinase would not be obvious to those familiar with the art obvious, but none backed up those arguments with statements from the prior art stating that such a step would not be necessary.

12. Claims 49, 51, 60 and 71-79 are allowable.

Conclusion

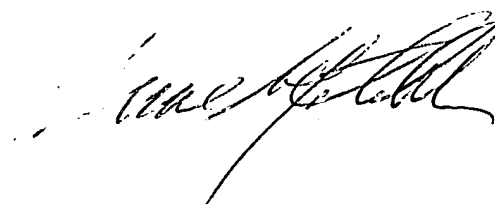
13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 17, 2004



**ANNE KUBELIK
PATENT EXAMINER**